

Nufarm Americas Inc.

11901 South Austin Avenue Alsip, IL 60803

Telephone: (708) 377.1330 Facsimile: (708) 377.1333

www.us.nufarm.com

October 22, 2013

Bo Davis (PM-25)
Document Processing Desk (APPL)
Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject:

**Bromoxynil Heptanoate Technical** 

EPA Reg. No. 35935-XXX

New Product Registration / R333 Action

Dear Mr. Davis:

With this submission Nufarm Limited is submitting Bromoxynil Heptanoate Technical to the Agency as a new Section 3 product for registration, R333 PRIA Guided Action.

Under PRIA III [FY 2014/15 Fee Schedule], it is our opinion that this action falls under category R333. We believe this is the appropriate category since this application is new product, with an unregistered source of Active Ingredient, and being submitted as a cite-all. As such, Nufarm anticipates this action to require a fee of \$18,893 and we would anticipate a 10-month & 21-day review time. Nufarm has prepaid the PRIA III fee.

To process this request please find on the adjoining CD an E-Submission with all documents thought to be needed to support to this registration submission.

If you should have any questions regarding this matter, please contact me at (708) 377-1421 or via e-mail at <a href="matthew.granahan@us.nufarm.com">matthew.granahan@us.nufarm.com</a>.

Sincerely,

Matthew Granahan Regulatory Manager

**Nufarm Limited** 

TRANSMITTAL DOCUMENT

Name and Address Nu

Nufarm Limited

4020 Aerial Center Parkway, Suite 101

Morrisville, NC 27560

Regulatory action in support of

Which this package is submitted: R-333 Submission

Bromoxynil Heptanoate Technical

**EPA Reg. No.:** 35935-RNL [NUP-13022]

**Transmittal Date:** November 20, 2013

Volume No. 1, Administrative Material: MRID Number

Cover Letter

Transmittal Document

EPA Form 8570-1 Application for Pesticide Registration

Copy of PRIA Payment

EPA Form 8570-4 CSFs – Basic

EPA Form 8570-34 Certification with Respect to Citation of Data

EPA Form 8570-35 Data Matrix (Public & Private)

Copy of Bayer LOA

Label Certification Certification with Respect to Label Integrity Form

Label 49226500

Volume No. 2 MRID Number

Product Chemistry Requirements (PC Part A)

Technical Bromoxynil Heptanoate, NUP-13022 OPPTS Sections 830.1550, 830.1600, 860.1620, 830.1670, 830.1700, 830.1750, 830.1800. Unpublished study by Nufarm Limited

Study No. RTP-13-070-REG. 69 pages Total **49226501** 

Volume No. 3 MRID Number

Product Chemistry Requirements (5BA)

Five -Batch Analysis of Bromoxynil Heptanoate TGAI, CA 3069

OPPTS Section 830.1700, 830.1800. Unpublished study by Nufarm Limited Study No. ABC-2012-19, 236 pages Tota

Study No. ABC-2012-19. 236 pages Total **49226502** 

Volume No. 4 MRID Number

Product Chemistry Requirements (5BA)

Method Validation Bromoxynil Heptanoate TGAI

OPPTS Section 830.1700, 830.1800. Unpublished study by Nufarm Limited Study No. ABC-2012-22. 249 pages Total

udy No. ABC-2012-22. 249 pages Total **49226503** 

Volume No. 5 MRID Number

Product Chemistry Requirements (PC Part B)

Physical and Chemical Characterization of Bromoxynil Heptanoate TGAI, CA 3069

OPPTS Sections 830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.7000, 830.7300.

Unpublished study by Nufarm Limited

Study No. ABC-2012-20. 82 pages Total **49226504** 

Company Official: Matthew Granahan, Regulatory Manager

Company Name: Nufarm Limited

Company Contact: Matthew Granahan Phone: (708) 377-1421